K014263

MAR 8 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
NewGen/Universal Mandibular System

General Information

Proprietary Name:	NewGen/Universal Mandibular System
Common Name:	Bone Plates Bone Fixation Fasteners
Proposed Regulatory Class:	Class II
Device Classification:	76 JEY 87 HWC
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 616-323-7700 x3295
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Robin L. Rowe Regulatory Affairs Representative Phone: 616-323-7700 x3295 Fax: 616-324-5412
Summary Preparation Date:	November 22, 2000

Intended Use

The Stryker Leibinger NewGen System is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.

Substantial Equivalence

EQUIVALENT PRODUCTS:

The Leibinger® NewGen/Universal System is substantially equivalent to the NewGen System K002619 which is a legally marketed devices.

Robin L. Rowe
Regulatory Affairs Representative
December 20, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Ms. Robin L. Rowe
Regulatory Affairs
Stryker Instruments
4100 East Milham Avenue
Kalamazo, Michigan 49001-6197

Re: K014263
Trade/Device Name: Newgen/Universal Mandibular System
Regulation Number: 872.4760
Regulation Name: Bone Plates, Bone Fixation System
Regulatory Class: II
Product Code: JEY
Dated: February 6, 2002
Received: February 7, 2002

Dear Ms. Rowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

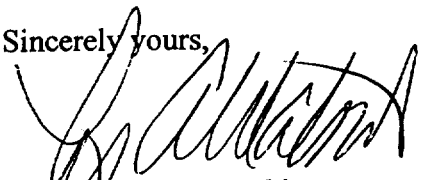
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Newgen/Universal Madibular System

Indication For Use:

The Stryker Leibinger Newgen/Universal Mandibular System is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH,Office of device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014263